AMENDMENT

In the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the application. Currently amended claims are shown with additions underlined and deletions in ~~strikethrough text~~. No new matter is added by this amendment.

1. (Currently Amended) A method of determining whether mass spectral data from a test serum is acceptable for analysis in a bioassay ~~quality assurance for a biological diagnostic using mass spectral data from an electrospray process~~, comprising:

selecting a diverse group of sera, the diverse group of sera having different characteristics;

diluting each serum of the diverse group of sera with a plurality of different diluents;

obtaining information associated with a mass spectrum of each of the diluted sera from the diverse group of sera using ~~the~~an electrospray process;

generating a control model based at least in part on the spectra obtained from the diverse group of sera, the control model including at least one ~~control~~ centroid located in an n-dimensional space defined by n mass spectral features included in the control model;

diluting a test serum with a test diluent;

performing mass spectrometry on the test serum to obtain a test spectrum associated with the test serum;

mapping the test spectrum ~~obtained from said performing~~ to the n-dimensional space;

if it is determined that the test spectrum maps to the n-dimensional space within an acceptable distance from said at least one centroid in the control model, certifying that ~~centroid, submitting~~ the test spectrum is acceptable for analysis in the bioassay ~~to the biological diagnostic~~.

2. (Canceled)

3. (Original) The method of claim 1, wherein said diluting each serum of the diverse group of sera includes diluting the sera with diluents having a predetermined diluent concentration, and said diluting a test serum with a test diluent includes diluting a test serum with a diluent having the same concentration as the diluent used to dilute each serum of the diverse group of sera.

4. (Original) The method of claim 1, wherein said diluting each serum of the diverse group of sera includes diluting the sera with diluents having a predetermined diluent concentration, and said diluting a test serum with a test diluent includes diluting a test serum with a diluent having a different concentration than the diluent used to dilute each serum of the diverse group of sera.

5. (Original) The method of claim 1, further comprising:

classifying a biological state from the spectrum based on a predetermined biological state model.

6. (Currently Amended) The method of claim 1, wherein if the test spectrum does not map to the n-dimensional space within an acceptable distance from the at least one centroid in the control model~~centroid~~, and the test diluent is a first diluent, the method further comprising:

repeating the steps of diluting a test serum, performing, mapping, and ~~determining~~ certifying for a second diluent different from said first diluent.

7. (Original) The method of claim 1, said selecting further comprising:

selecting at least two different sera from a pool of diverse sera, the pool of diverse sera consisting of: sera from healthy males, sera from healthy females, sera from males afflicted with a disease, sera from females afflicted with a disease, sera from persons of different races, and sera from people of different ages.

8. (Previously Presented) The method of claim 1, wherein said generating includes:

identifying at least one cluster in common to the sera of the diverse group of sera and the plurality of different diluents; and

selecting only one cluster as the control ~~centroid~~ of the control model.

9. (Original) The method of claim 1, wherein the obtaining information includes:

obtaining information on sera diluted with two different diluents, the diluents including at least acetonitrile and methanol.

10. (Original) The method of claim 1, wherein the test diluent is one of the plurality of different diluents.

11. (Original) The method of claim 1, wherein the test diluent is not one of the plurality of different diluents.

12. (Currently Amended) A method of determining whether mass spectral data from a test serum is acceptable for analysis in a bioassay ~~quality assurance~~ for a biological diagnostic employing a control model generated based on mass spectra obtained from sera analyzed following an electrospray process, the spectra being associated with a plurality of different sera and a plurality of different diluents, the control model including at least one ~~control~~ centroid located in an n-dimensional space defined by n mass spectral features included in the control model, comprising:

diluting a test serum using a test diluent;

ionizing the diluted test serum using an electrospray process;

performing mass spectrometry on the ionized diluted test serum to obtain test spectral data associated with the test serum and the test diluent; and

mapping the test spectrum to the n-dimensional space; and

if the test spectrum maps to the n-dimensional space within an acceptable distance from the ~~control~~ centroid, certifying that the test spectrum is acceptable for analysis in the bioassay ~~submitting the test spectrum to the biological diagnostic~~.

13. (Currently Amended) The method of claim 12,

wherein the bioassay determines ~~submitting includes submitting the test spectrum to the biological diagnostic to determine~~ if the test serum exhibits a particular biological state.

14. (Currently Amended) The method of claim 13, wherein the test diluent is one of acetonitrile and methanol.

15. (Canceled)

16. (Previously Presented) The method of claim 1, wherein said plurality of different diluents includes acetonitrile and methanol.

17. (Previously Presented) The method of claim 1, wherein said diluting each serum of the diverse group of sera includes creating a plurality of dilutions of each serum with a diluent at a plurality of concentrations.

18. (Previously Presented) The method of claim 17, wherein said plurality of concentrations ranges between 1:250 to 1:1000.

19. (Canceled)

20. (Previously Presented) The method of claim 1, wherein said diluting a test serum includes diluting a test serum with a known diluent.

21. (Previously Presented) The method of claim 1, wherein said diluting a test serum includes diluting a test serum with one of the plurality of different diluents used to dilute the diverse group of sera.

22. (Previously Presented) The method of claim 1, wherein said diluting a test serum includes diluting a test serum with a test diluent different than any of the plurality of different diluents used to dilute the diverse group of sera.

23. - 26. (Canceled)

27. (Currently Amended) A method of determining whether mass spectral data from a test serum is acceptable for analysis in a bioassay~~quality assurance for a biological diagnostic using mass spectral data from an electrospray process~~ using sera diluted with a first diluent, comprising:

providing in an n-dimensional space defined by n mass spectral features a location of at least one ~~control~~ centroid associated with a first~~one~~ diluent and that distinguishes the first~~one~~ diluent from at least one second diluent;

using an electrospray ionization process, ionizing a test serum diluted with the at least one second ~~a test~~ diluent to generate a test mass spectrum;

mapping the test mass spectrum to the n-dimensional space; and

if the spectrum maps to the n-dimensional space within an acceptable distance from the at least one ~~control~~ centroid associated with the first diluent, certifying the spectrum for analysis in the bioassay~~with the biological diagnostic~~.

28. (Currently Amended) A ~~quality control~~ method of determining whether mass spectral data from a test serum using an electrospray process is acceptable for analysis in~~for~~ a bioassay that generates mass spectral data from a sample that is diluted by a diluent, comprising:

providing a location in an n-dimensional space defined by n mass spectral features of at least one ~~control~~ centroid associated with a preferred diluent concentration and composition;

providing a location in the n-dimensional space of at least one test centroid associated with a test sample;

comparing the at least one test centroid to the at least one ~~control~~ centroid associated with a preferred diluent to determine the displacement in the n-dimensional space of the at least one test centroid ~~from the at least one control centroid~~; and

determining a degree of error between the test centroid and the ~~control~~ centroid associated with the preferred diluent;

wherein the test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one ~~control~~ centroid associated with a preferred diluent is within an acceptable distance.

29. (Currently Amended) The ~~quality control~~ method of claim 28, wherein the bioassay determines if the test serum exhibits a particular biological state~~the test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one control centroid is within an acceptable distance~~.

30. (Currently Amended) The ~~quality control~~ method of claim 28, wherein the sample is serum.

31. (Currently Amended) The ~~quality control~~ method of claim 28, wherein the mass spectral data is generated by an electrospray ionization technique.

32. (Currently Amended) A ~~quality control~~ method of determining whether mass spectral data from a test serum using an electrospray process is acceptable for analysis in ~~for~~ a bioassay that generates mass spectral data from a sample that is diluted by a diluent, comprising:

providing a location in an n-dimensional space defined by n mass spectral features of at least one ~~control~~ centroid associated with a preferred diluent concentration and composition;

providing a location in the n-dimensional space of at least one test centroid associated with a test sample; and

determining ~~comparing the at least one test centroid to the at least one control centroid to determine~~the displacement in the n-dimensional space of the at least one test centroid from the at least one ~~control~~ centroid associated with a preferred diluent; wherein the test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one centroid associated with a preferred diluent concentration and composition is within an acceptable distance~~magnitude of the displacement is an indicator as to reliability of the bioassay applied to the test sample~~.

33. (Currently Amended) The ~~quality control~~ method of claim 32, wherein the bioassay determines if the test serum exhibits a particular biological state~~test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one control centroid is within an acceptable distance~~.

34. (Currently Amended) The ~~quality control~~ method of claim 32, wherein the sample is serum.

35. (Currently Amended) The ~~quality control~~ method of claim 32, wherein the mass spectral data is generated by an electrospray ionization technique.

36. (Currently Amended) A method of determining whether mass spectral data from a test serum using an electrospray process is acceptable for analysis in a bioassay quality assurance for a biological diagnostic employing a control model generated based on mass spectral features associated with a sample that includes serum and a preferred concentration of diluent and composition of diluent, the control model including at least one ~~control~~ centroid located in an n-dimensional space defined by n mass spectral features associated with a sample that includes serum and a preferred concentration of diluent and composition of diluent and included in the model, comprising:

performing mass spectrometry on a test sample that includes serum and a diluent having a concentration and a composition to obtain a test spectrum associated with the test sample; and

mapping the test spectrum to the n-dimensional space; and

if the test spectrum maps to the n-dimensional space within an acceptable distance from the at least one ~~control~~ centroid, certifying that the concentration of the diluent and the composition of the diluent are acceptable for the bioassay~~biological diagnostic~~.

37. (Previously Presented) The method of claim 36, wherein said performing mass spectrometry includes performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

38. (Currently Amended) The method of claim 36, wherein the bioassay is ~~said biological diagnostic is a disease model~~ capable of determining if the test serum exhibits a disease state ~~associated with the disease model~~.